Medical Device and Drug Safety Programs-AB 1277 FAQ's:

1. **What is AB 1277?**

   This is a new law to amend sections 111550 and 111635 of the CA Health and Safety Code and describes a new licensing process for drug and medical device manufacturers. The full text of the new law can be found on our website at http://www.cdph.ca.gov .

2. **When does AB 1277 take effect?**

   The new law takes effect on January 1, 2013.

3. **What if I apply for a new license in 2012?**

   The new law would not be in effect. The existing law requires the department to inspect the place of business of each drug or medical device manufacturer prior to issuing a license. You need only to file an application and furnish the license fee. The current fee is set at $1600 for a new license. The new license is valid for one (1) year. An inspection will be arranged.

4. **What if I renew my existing license in 2012?**

   The new law would not be in effect. The existing law requires the department to inspect the place of business of each drug or medical device manufacturer prior to issuing a license. You need only to file a renewal application and furnish the renewal fee. The current fee is set at $2600 for a renewal license. The renewal is valid for two (2) years. An inspection will be arranged.

5. **What if I apply for a new license in 2013 or apply for a new license in the future?**

   The new law would be in effect. You will need to file an application and furnish the fee that is specified on the application. Currently, the fee is set at $1600 for a new license. In addition, the new law states that "the department shall receive from each place of business documentation that evidences ownership and any of the following:
   (1) The place of business is operating pursuant to a valid biologics license issued by the United States Food and Drug Administration in compliance with Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262).
   (2) The place of business is operating with a valid establishment registration pursuant to Section 510 of the federal act (21 U.S.C. Sec. 360). This documentation shall include an attestation from an officer of the place of business that a federal inspection was completed within the two years prior to the date of attestation.
   (3) The place of business is operating in compliance with audits conducted pursuant to the International Standards Organization (ISO) 9000 series, ISO 13485:2003 quality management systems standards, ISO 15378:2006 quality management systems standards, pursuant to Parts 210 and 211 of Title 21 of the Code of Federal Regulations, or pursuant to Part 820 of Title 21 of the Code of Federal Regulations.
   (4) The place of business is operating pursuant to an approved investigational new drug issued by the federal

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Food and Drug Administration pursuant to Section 312.20 of Title 21 of the Code of Federal Regulations or pursuant to an approved investigational device exemption issued by the federal Food and Drug Administration pursuant to Section 812.20 of Title 21 of the Code of Federal Regulations."

6. **What if I renew my license in 2013 or apply for a renewal license in the future?**

   The new law would be in effect. You will need to file an application and furnish the license fee that is specified on the application. Currently, the fee is set at $2600 for a renewal license. Refer to question 5 above to determine what documentation you need to send to the department.

7. **What about my documentation package?**

   If the department receives documentation that satisfies the requirements (refer to question 5 above) the department shall not inspect the place of business prior to issuing a license. If the department does not receive the documentation required, the department shall inspect the place of business prior to issuing a license.

8. **What does manufacture mean?**

   "Manufacture" means the preparation, compounding, propagation, processing, or fabrication of any food, drug, device, or cosmetic. The term "manufacture" includes repackaging or otherwise changing the container, wrapper, or labeling of any food, drug, device or cosmetic. The term "manufacture" does not include repackaging from a bulk container by a retailer at the time of sale to its ultimate consumer. (California Health and Safety Code Section 109970)

9. **What is a drug?**

   "Drug" means any of the following:
   (a) Any article recognized in an official compendium.
   (b) Any article used or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or any other animal.
   (c) Any article other than food, that is used or intended to affect the structure or any function of the body of human beings or any other animal.
   (d) Any article used or intended for use as a component of any article designated in subdivision (a), (b), or (c) of this section.

   The term "drug" does not include any device.

   (California Health and Safety Code Section 109925)

10. **What is a device?**

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"Device" means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or similar related article, including any component, part, or accessory, that is any of the following:

(a) Recognized in the National Formulary or the United States Pharmacopoeia, or any supplement to them.
(b) Intended for the use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease in humans or any other animal.
(c) Intended to affect the structure or function of the body of humans or any other animal and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and that is not dependent upon being metabolized for the achievement of any of its principal intended purposes. (California Health and Safety Code Section 109920)

11. **When would I be subject to an inspection?**

If the department does not receive the documentation required by Health and Safety Code Section 111635(a), the department shall inspect the place of business prior to issuing a license; and

Any place of business where a drug or device is manufactured and the manufacturer has received a license, the department shall make investigations or inspections when any of the following occur:
(1) The department becomes aware of an issue and makes a determination that the health and safety of the public is at risk.
(2) A complaint has been registered with the department and the department makes a determination that the health and safety of the public is at risk.
(3) A notification has been sent by the United States Food and Drug Administration to the department that requests assistance regarding any Class I or II recall action memorandum.
(4) The United States Food and Drug Administration has requested assistance for enforcement activities, including, but not limited to, embargoes, seizures, or injunctions.

12. **What if I have more questions?**

Please contact us at (916) 650-6500 or FDBMedDevice@cdph.ca.gov. You may also visit our website at http://www.cdph.ca.gov .